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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/125,005	07/30/1998	DANIEL CAPUT	IVD-913	7322

27546 7590 04/02/2004

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EXAMINER

UNGAR, SUSAN NMN

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 04/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/125,005

Applicant(s)

CAPUT ET AL.

Examiner

Susan Ungar

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 22 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-32 and 35-38 is/are pending in the application.
- 4a) Of the above claim(s) 6-32 and 35-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

1. The Amendment filed December 22, 2003 in response to the Office Action of June 18, 2003 is acknowledged and has been entered. New claim 39 has been added. Claims 1-5 and 39 are currently being examined.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. The following objections to the specification are being maintained.

Objection to the specification recited in Section 3, page 7 of the paper mailed June 18, 2003.

The objection is maintained as Applicant neither distinctly and specifically pointed out the supposed errors in the objection nor amended the claims as required.

4. The following rejections are being maintained:

Claim Rejections - 35 USC § 101

5. Claims 1-5 remain rejected and newly added claim 39 is rejected under 35 USC 101 for the reasons previously set forth in the paper mailed June 18, 2003, section 2, pages 2-7.

Applicant argues that in light of Examiner's admission on the record that SEQ ID NO:6 is residue by residue identical to the p73 amino acid of WO99/66946 and in light of the teaching by Tominaga et al that p73 accumulates in various tumor cells and the Ikawa et al teaching that p73 is differentially expressed in a number of cancers compared to normal tissue control, and the Tominaga et al teaching that sera from cancer patients containing p73 antibodies are detected by reaction with p73, the full elucidation of the role of p73 in cancer is irrelevant to its use in detecting p73 antibodies in the sera of cancer patients and regardless of whether p73 is expressed *in vivo* or *in vitro*, the p73 of Tominaga et

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al, whatever isoform it happens to be, detects p73 antibodies in the sera of cancer patients.

The argument has been considered but has not been found persuasive because, as previously set forth, no nexus has been provided, either in the specification or the art of record that suggests that it is the SEQ ID NO:6 protein isoform which accumulates in various tumor cells and is differentially expressed in a number of cancers compared to normal control. Further, the teaching in the specification that antibody to expressed SEQ ID NO:6 did not bind to SEQ ID NO:6 in the cell line from which the polynucleotide encoding SEQ ID NO:6 was isolated, raised the important question as to whether or not SEQ ID NO:6 is actually expressed *in vivo*. Although WO 99/66946 teaches that expressed p73, SEQ ID NO:6 of the instant invention, induced apoptosis and suppresses growth in HPV E6 expressing human cancer cells in culture, for the reasons of record, this finding does not provide utility for the claimed invention. Further as drawn to the Ikawa et al reference, the reference is not commensurate in scope with the claimed invention given that the reference is drawn to polynucleotide expression and not to protein expression which cannot be predictably correlated to protein expression for the reasons of record.

Applicant further argues that even if p73 is not differentially expressed in all possible tumor types, it does provide a means of detecting those tumors in which it is differentially expressed and regardless of whether p73 is expressed *in vivo* or in cell culture, the fact is that the p73 of Tominaga et al was effective in detecting p73 antibodies in the sera of cancer patients and given that p73 and SR-p70 are identical, Applicants do indeed teach a utility for the claimed invention.

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The argument been considered but has not been found persuasive since a review of Tominaga did not reveal that the construct provided by D. Caput is the p73 disclosed in WO 99/66946, and given the known splice variants of p73, no nexus has been established between p73 of Tominaga et al and the p73 disclosed in WO 99/66946 of El-Deiry. Thus, no nexus can be established between the p73 of Tominaga and the claimed SR-p70, SEQ ID NO:6. Applicants arguments have not been found persuasive and the rejection is maintained.

Claim Rejections - 35 USC §112

6. Clams 1-5 remain rejected and new claim 39 is rejected under 35 USC 112, first paragraph for the reasons previously set forth in the paper mailed June 18, 2003, section 3, page 7.

Because applicant did not distinctly and specifically point out the supposed errors in the rejection, the rejection is maintained.

7. Claims 1-5 remain rejected and new claim 39 is rejected under 35 USC 112, first paragraph for the reasons previously set forth in the paper mailed June 18, 2003, section 5, pages 8-13.

Applicant argues that the Examiner acknowledges that Tominaga et al teach the detection of p73 autoantibodies in patients with various types of cancer and that SEQ ID NO:6, SR-p70 is identical to p73, accordingly the instant specification fully meets the requirements of 35 USC 112, first paragraph.

The argument has been considered but has not been found persuasive because, for the reasons set forth above, given the known splice variants of p73, no nexus has been provided between the p73 useful for detecting cancer-related autoantibodies of Tominaga et al and the instantly claimed invention. Applicants arguments have not been found persuasive and the rejection is maintained.

8. No claims allowed.
9. All other objections and rejections recited in the paper mailed June 18, 2003 are hereby withdrawn.
10. Applicant's amendment necessitated the new grounds of rejection. Thus, **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

11. This application contains claims drawn to inventions previously nonelected with traverse. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

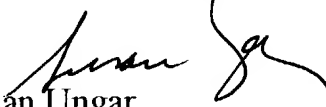
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvette Eyler, can be reached at 571-272-0871. The fax phone number for this Art Unit is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.



Susan Ungar
Primary Patent Examiner
March 31, 2004